Office Action Summary	Application No.	Applicant(s)	
	10/772,781	GIN ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-22,26,29,46,47,101,102 and 104-109* is/are pending in the application.

4a) Of the above claim(s) *9-11 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,26,29,46,47,101,102 and 104-109* is/are rejected.

7)☒ Claim(s) *12 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20110224* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed November 3, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The claims filed November 3, 2010 are entered.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-4, 6-8, 12, 13, 26, 46, 47 and 102-109 were rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (WO 99/06030, already of record) in view of Lin et al. (Journal of Controlled Release 2001, already of record) and Gohlke (US 2002/0054917, already of record). The rejection is maintained in regard to claim 109 and withdrawn in regard to claims 1-4, 6-8, 12, 13, 26,46,47 and 102-108.

Applicant's Arguments

The Applicants have amended the relevant section of independent claim 1 to specify: "a flavoring agent comprising essential oils, and optionally, constituents of essential oils, the essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge." Applicants submit that none of the cited art teach or suggest the limitation of: "essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge." The maximum amount of essential oil in a tablet according to Friedman is 1/5th of 40%, or 8 wt. %. This is considerably lower than "essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge," as specified in amended claim 1. Applicants also note that none of the cited references disclose the limitation "wherein the micronized ethylcellulose and the flavoring agent are admixed and present in the dosage form at a weight ratio of approximately 1 : 1.5 to 1.5:1," as specified in independent claims 1 and 109. Further, the weight percentage (25 - 49.5%) or the weight ratio (1:1.5 to 1.5:1) of essential oil in the claimed dosage form represents an amount of essential oil that is much higher than that taught by Friedman. Sudden oral delivery of such large amount of essential oil by the method of Gohlke (bolus delivered by chewable lozenge) or Lin (pulsatile delivery using a delayed release lozenge) would result in undesirable effects on the user, which is avoided by the claimed dosage form which "gradually releas[es] the flavoring agent over an extended time period in the range of about 15 minutes to about 4 hours." Applicants submit that a prima facie case for obviousness has not been made.

Examiner's Response

In regard to claim 109, Applicant has not amended the claim to limit the flavoring agent to essential oil. The claim recites essential oil constituents and therefore is still encompassed by the combination of references. In regard to the ratio, Friedman discloses ethyl cellulose comprises 11 percent to 53 percent by weight (page 2, lines 15-17) and the essential oil extract comprises 0.5 percent to about 40 percent weight by weight (page 6, lines 7-9). Therefore Friedman discloses the ratios recited by the instant claims. Friedman discloses a delayed release dosage form comprising ethyl cellulose, which controls the release of the active. Therefore, formulating these dosage forms into soft lozenges, such as that disclosed by Gohike, with the ethyl cellulose of Lin et al. should not produce a sudden release of oil because the ethyl cellulose will delay the release of the oils from the lozenge.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 1-4, 6-8, 26, 29, 46, 47, 102 and 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. (US 4,572,832) in view of Lin et al. (Journal of Controlled Release 2001, already of record), in further view of Kulkarni et al. (US 2003/0206942).

Kigasawa et al. disclose a soft buccal comprising an active, a water-soluble protein, a polyhydric alcohol and a fatty acid ester or/and a carboxyvinyl polymer. The buccal has various advantages such as good feeling in use, good retainability within the mouth, slow release, improved absorbability of drug through the mucosa, improved

bioavailability, etc., and therefore can be used as an excellent pharmaceutical preparation for administration to the mucous membrane of the mouth (Abstract). The active comprises 0.05 to 60 percent of the soft buccal (col. 3, lines 5-10). Actives include drugs that act on the oral cavity (col. 1, lines 52-55). The buccals are formed into disk having a thickness ranging from 0.5 to 3 cm (col. 6, lines 16-26), which reads on a lozenge. The protein comprises 0.5 to 150 parts by weight of the drug (col. 3, lines 61-65). The polyhydric alcohols control and maintain the softness of the soft buccal and also control the rate of dissolution and disintegration (col. 4, lines 5-9). The polyhydric alcohols include ethyl cellulose and comprise 0.01 to 3 parts by weight of the protein (col. 4, lines 54-56). Other components include flavors such as lemon oil and saccharin sodium, preservatives and colors (col. 5, lines 56-68), encompassing claims 26, 29, 46 and 47. Additives are not always used for one purpose alone (col. 6, lines 14 and 15). The soft buccals require at least 10 minutes for their dissolution or disintegration in the mouth (col. 7, lines 39-43).

The reference differs from the instant claims insofar as it does not disclose that the ethyl cellulose is micronized ethyl cellulose or that an essential oil is present in the compositions with a concentration ranging from approximately 25 wt% to 49.5 wt% of the lozenge.

Lin et al. disclose the effects of micronized ethyl cellulose (EC) powders on the release rate of drugs. Ethyl cellulose is well-known and is often used as a rate-controlling membrane to modulate the drug release from dosage forms. The particle size of EC plays an important role in controlling drug release (page 322, col. 1,

paragraph 2 to col. 2, paragraph 1). The viscosity of the EC powders used ranged from 6.2 to 84.9 cps (Table 1), encompassing “approximately 90 cP” and encompasses claims 6, 7 and 105-107. Ethyl cellulose with larger particle size exhibit more rapid disintegration and leads to faster drug release (page 323, col. 2, last paragraph). The particle size of the EC used include 4.0, 4.6, 6.0, 167.5, 224.3 and 398.0 micro meters.

The reference differs from the instant claims insofar as it does not disclose the micronized EC powders are used in a soft lozenge with an essential oil.

The rate of release of the active is dependent on the type of ethyl cellulose and the size of the ethyl cellulose used. It would have been obvious to use micronized ethyl cellulose as the ethyl cellulose in the compositions of Kigasawa et al. motivated by the desire to use ethyl cellulose that will give a slower rate of release than ethyl cellulose with a larger particle size and to obtain the desired rate of release of the active as disclosed by Lin et al.

In regard to the amount and particle size of ethyl cellulose, the amount of ethyl cellulose and its particle size control the rate of release of the disclosed active. It would have been obvious to one of ordinary skill in the art to have adjusted the amount of ethyl cellulose and used a certain particle size of micronized ethyl cellulose, such as about 20 microns as recited in the instant claim 104, in the compositions of the combined teachings of Kigasawa et al. and Lin et al. motivated by the desire to obtain the desired rate of release of the active.

The prior art does not disclose the exact claimed values of 25 wt% to 49.5 wt% ethyl cellulose and a release time of 15 minutes to about 4 hours, but does overlap

disclosing 0.01 to 3 parts by weight of the protein, and at least 10: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Furthermore, the amount of ethyl cellulose controls the rate of release. It would have taken no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of ethyl cellulose to achieve the desired rate of release of the active to 15 minutes to 4 hours.

The combined teachings of the primary and secondary references differs from the instant claims insofar as it does not disclose an essential oil is the active in the dosage forms and the oil has a concentration ranging from 25 to 49.5 wt% by weight of the composition.

Kulkarni et al. disclose consumable films adapted to adhere and dissolve in the oral cavity (Abstract). The consumable film may include one or more of the following ingredients, including, but not limited to, water, antimicrobial agents, additional film forming agents or water soluble polymers, plasticizing agents, flavorings, sulfur precipitating agents, saliva stimulating agents, cooling agents, surfactants, stabilizing agents, emulsifying agents, thickening agents, binding agents, coloring agents, triglycerides, polyethylene oxides, propylene glycols, sweeteners, fragrances, preservatives and the like (paragraph 0008). Essential oils are used for their antimicrobial efficacy and generally comprise up to 30% by weight of the composition (paragraph 0026). Preservatives may be added to the compositions and may comprise 0.001 to about 5% of the compositions, encompassing claim 108.

The reference differs from the instant claims insofar as it does not disclose the compositions are lozenges comprising a sustained release matrix including micronized ethyl cellulose.

It would have been obvious to one of ordinary skill in the art to have used an essential oil in amounts of up to 30% as an antimicrobial agent to act on the oral cavity and a preservative ranging from 0.001 to 5% in the compositions of the combined teachings of Kigasawa et al. in view of Lin et al. motivated by the desire to use an ingredient, the essential oil, that is used to treat the oral cavity as antiseptics to eradicate plaque-producing germs that cause dental plaque, gingivitis and bad breath and to use the preservative in an amount suitable for oral compositions as disclosed by Kulkarni et al.

The prior art does not disclose the exact claimed values of 25 wt% to 49.5 wt% of essential oil and 1 to 45% additive (preservative), but does overlap disclosing up to 30% essential oil and 0.001 to 5% preservative: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

2) Claims 1-4, 6-8, 26, 29, 46, 47, 101, 102 and 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ventouras (US 6,183,775, already of record) in view of Lin et al. (Journal of Controlled Release 2001, already of record), in further view of Day et al. (US 2003/0003219) and Gohlke (US 2002/0054917, already of record).

Ventouras discloses a controlled release lozenge having pleasant organoleptic properties, said lozenge consisting essentially of (a) a soluble filler which is selected from the group consisting of maltitol, xylitol, sorbitol, mannitol, lactose, dextrose, saccharose, fructose, and mixtures thereof (encompassing instant claims 26, 29, 47, 101 and 108); (b) an insoluble film forming agent which is capable of forming an insoluble matrix, said insoluble film forming agents include ethyl cellulose (encompassing the instant claims); (c) a swellable polymer which is selected from the group consisting of xanthan gum, guar gum, alginic acid or a salt thereof, pectin, polyvinyl alcohol, polysaccharide, and cellulose derivatives; and (d) at least one active substance (Abstract). The filler comprise 50 to 99% of the composition (col. 1, lines 53-55). The insoluble film forming agent comprises 0.5 up to 30% of the total composition (col. 2, lines 32-36). The swellable polymer comprises 0.5 to 30% of the composition (col. 3, lines 1-4), which encompasses an adhesion agent in claim 47 and about 1 wt% in claim 108. The active substances include analgesics and agents against dental plaque (col. 3, lines 20-24). Usual auxiliaries include sweeteners, colorants, flavors and aromas. (col. 3, lines 32-34), encompassing claim 26, 29 and 46. The delivery of the active occurs in a controlled release manner normally within a period of from 15 minutes up to 90 minutes, or within an even longer period of time.

The reference differs from the instant claims insofar as it does not disclose that the ethyl cellulose is micronized ethylcellulose or that an essential oil is present in the compositions with a concentration ranging from approximately 25 wt% to 49.5 wt% of the lozenge.

Lin et al. disclose the effects of micronized ethyl cellulose (EC) powders on the release rate of drugs and is discussed above. The reference differs from the instant claims insofar as it does not disclose the micronized EC powders are used in a soft lozenge with an essential oil.

The rate of release of the active is dependent on the type of ethyl cellulose and the size of the ethyl cellulose used. It would have been obvious to use micronized ethyl cellulose as the ethyl cellulose in the compositions of Ventouras et al. motivated by the desire to use ethyl cellulose that will give a slower rate of release than ethyl cellulose with a larger particle size and to obtain the desired rate of release of the fragrance as disclosed by Lin et al.

In regard to the amount and particle size of ethyl cellulose, the amount of ethyl cellulose and its particle size control the rate of release of the disclosed active. It would have been obvious to one of ordinary skill in the art to have adjusted the amount of ethyl cellulose and used a certain particle size of micronized ethyl cellulose, such as about 20 microns as recited in the instant claim 104, in the compositions of the combined teachings of Ventouras and Lin et al. motivated by the desire to obtain the desired rate of release of the active.

The prior art does not disclose the exact claimed values of 25 wt% to 49.5 wt% ethyl cellulose and a release time for the active of 15 minutes to 4 hours, but does overlap disclosing 0.5 up to 30% insoluble film forming agent and 15 minutes up to 90 minutes or an extended period for the rate of release: in such instances even a slight

overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Furthermore, the amount of ethyl cellulose controls the rate of release. It would have taken no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of ethyl cellulose to achieve the desired rate of release of the active 2 hours as recited in instant claim 4.

The combination of the primary and secondary references differs from the instant claims insofar as they do not disclose an essential oil is in the lozenge with a concentration ranging from 25 to 49.5 wt%.

Day et al. disclose confectionery compositions for oral care (Abstract). The compositions are formulated into breath mints, low boiled candy, hard boiled candy, coated candy, lozenges, oral pasta, pressed mints, throat drops and the like (paragraph 0002). The compositions comprise anti-plaque agents. Anti-plaque agents are any substances which inhibit the accumulation of bacterial deposits on the surfaces of the oral cavity. Examples include xylitol and other anti-microbial agents (paragraph 0074). Essential oils are disclosed as being anti-bacterial agents and may comprise from 0.0001% to about 30% by weight of the composition (paragraph 0081).

The reference differs from the instant claims insofar as it does not disclose a lozenge comprising ethyl cellulose or that the lozenges are soft and pliable.

It would have been obvious to one of ordinary skill in the art to have used an essential oil in amounts of up to 30% as an agent against dental plaque in the composition of the combined teachings of Ventouras in view of Lin et al. motivated by

the desire to use an ingredient that is suitable for killing bacteria which would lead to inhibiting the accumulation of bacterial deposits, as disclosed by Day et al.

The prior art does not disclose the exact claimed values of 25 wt% to 49.5 wt% of essential oil, but does overlap disclosing 0.0001 % to about 30% by weight: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

When the soluble filler (a) and the swellable polymer (c) of Ventouras are disclosed at their lowest amounts, 50% and 0.5% respectively, the active may only comprise 24.5% when ethyl cellulose is 25%. The instant claims recite the limitation "approximately" 25%, which reads on amounts lower than 25%, such as 24.5%. Thus the combination of references encompasses the limitations of the instant claims.

The combination of Ventouras, Lin et al. and Day et al. differs from the instant claims insofar as it does not disclose the lozenge is soft or pliable.

Gohlke is used as a general teaching to show chewable lozenges are used to deliver active components to the oral cavity. Chewable lozenges are mucosal delivery devices (paragraph 0030). Lozenges enhance the benefits associated with absorption through the oral cavity because they are designed to be dissolved slowly in the mouth and they may also be chewable. Dosage forms that are chewable or that are appropriate for sucking can be additionally designed to encourage salivation. Such dosage forms include lozenges, particularly chewable lozenges and chewable tablets. The addition of natural or artificial flavoring also encourages retention of the dosage form within the mouth, particularly with children, so that there is greater transfer of the

active components through the lining of the oral cavity and into the bloodstream and/or the lymphatic system (paragraph 0047). Chewable lozenges may also be chewed for prolonged periods of time (paragraph 0056). The compositions may comprise fillers, sweeteners, colorants and sorbitol (paragraph 0048 and 0052), encompassing claims 26, 46 and 47.

The reference differs from the instant claims insofar as it does not disclose the lozenges comprise ethyl cellulose in mixture with an essential oil or the recited amounts of each component.

It would have been obvious to one of ordinary skill in the art to have formulated a chewable lozenge comprising the compositions of the combined teachings of Ventouras, Lin et al. and Day et al. motivated by the desire to use a dosage form that enhances the benefits associated with absorption through the oral cavity because they are designed to be dissolved slowly in the mouth and can be chewed for prolonged periods of time as disclosed by Gohlke.

Response to Declaration in View of the New Rejections

Declaration under 37 CFR 1.132 by Jerry Gin

Applicant has made the composition of Example I disclosed by Alderman et al. to show that the compositions of the reference are not the same as those of instant. This supports that the compositions of Alderman are not soft dosage forms.

Response to Declaration

The Declaration is not persuasive in regard to new rejections.

Ventouras disclose lozenges comprising ethyl cellulose and an active ingredient in general but does not disclose characteristics of the lozenges. Gohlke discloses why one of ordinary skill in the art would desire a chewable (soft) lozenge thereby providing the motivation of why one of ordinary skill in the art would want to make the compositions of Ventouras et al. in view of Lin et al. and Day et al into soft lozenges.

Kigasawa et al. disclose soft buccals comprising ethyl cellulose and an active having a concentration ranging from 0.05 to 60% by weight. Kulkarni et al. discloses essential oils may be use in amounts of up to 30% (US 2003/0206942). This would provide motivation to one of ordinary skill in the art to add up to 30% essential oil in a soft composition disclosed by Kigasawa et al., encompassing the instant claims.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter:

Claims 12 and 13 appear to have allowable subject matter. The claims recite the essential oil a being a mint oil. The art does not appear to disclose using such a large amount of mint oil in an oral composition or in an oral composition with such a large amount of ethyl cellulose (above 25%). Maxwell et al. (US 2004/0086546) disclose flavor such as peppermint and spearmint or other mint oils may be used in amounts ranging from 0.1 to about 15 weight percent of an edible film, but does not disclose

larger amounts, a lozenge or ethyl cellulose. Therefore it appears that the claims are distinct over the prior art with regard to the amount of a mint essential oil.

Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-4, 6-8, 26, 29, 46, 47, 101, 102 and 104-109 are rejected.

Claims 9-11, 14-22 and 76

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
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